

REMARKS

Claims 4-30, 48-52 are pending in the application. Claims 4-30 and 48-52 have been rejected. Claims 4, 5, 8, 14, 16, 24, and 48-52 have been amended. Previously withdrawn claims 1-3, 31-47, and 53 have been cancelled.

Examiner Interview

On October 25, 2006 an Examiner Interview was conducted via telephone. The claimed invention was discussed as well as the rejections to the claims. During the interview the Examiner indicated that the field of the invention was a crowded one and referenced several additional references that have not been applied.

Claim Amendments

Claims 4, 5, 8, 14, 16, 24, and 48-52 have been amended to clarify that the historical subject compliance data and historical protocol data are from a previous clinical trial while the subject compliance data is from the current clinical trial.

Claim Rejections – 35 USC § 102

Claims 4-30 and 48-52 are rejected under 35 U.S.C. §102(e) as being anticipated by Stark et al (U.S. Patent No. 6,827,670. hereinafter, Stark). Applicants respectfully traverse the rejection.

Summary of Stark (U.S. Patent No. 6,827,670)

The Stark reference is directed to a system for treating orthopedic injuries by presenting a set of treatment protocols; approving a treatment protocol from among the presented set of treatment protocols; capturing information identifying the approved treatment protocol from among the set of presented protocols; and generating information from the captured information into a form compatible with a handheld computer adapted for connection to an orthopedic sensor system. The generated information includes parameters of the identified approved treatment protocol.

Claims 4 and 48

Amended claim 4 is a method claim and amended claim 48 is a medium claim with instructions for executing the method of amended claim 4. Stark fails to disclose each and every element of amended claims 4 and 48. Specifically, Stark discloses neither the step of providing at least one of historical compliance data and historical protocol data from a previous clinical trial nor the step of generating at least one preferred compliance threshold.

The passages indicated by the Examiner as disclosing the first step of providing historical compliance data (Col 5, ln 64-col 6, ln1; col 7, ln 57-60; col 11, ln 40-48; Fig. 11) actually discloses monitoring compliance over a 10 day period which is provided to the central computer. This is not providing historical compliance data as set forth in amended claims 4 and 48. Historical subject compliance data is not the same as subject compliance information. Historical subject compliance data is compliance data from previous clinical trials. Subject compliance information is the information regarding compliance collected during the current clinical trial. The cited passages are directed collecting compliance data for the currently prescribed regimen. The fact that this is actually current compliance data is reinforced by the Examiner when the same citations are referenced as disclosing the step of obtaining subject compliance information set forth in claim 16. Thus, Stark is not disclosing providing at least one of historical compliance data and historical protocol data from a previous clinical trial as set forth in amended claims 4 and 48.

In the Response to Arguments section of the Office Action, the examiner states there is no disclosure in the specification that makes a distinction between “historical subject compliance data” and “subject compliance information.” Applicants believe such distinction does exist in the specification (see page 8) and have amended the claims to further clarify that historical data is data from a previous clinical trial while compliance data is from the current clinical trial.

The step of generating at least one preferred compliance threshold by quantitative analysis of at least one of the group of the historical subject compliance data and the historical protocol data is also not disclosed by Stark. The generation of a preferred compliance threshold provides and indicator of non-compliance. That is, the generated compliance threshold is used during the current clinical trial to determine whether a subject is complying with the clinical trial

while participating in the clinical trial. This is indicated by dependent claims 5-6 wherein obtained compliance information is compared to the compliance threshold during the current clinical trial to determine if action is needed and then prompting action if action is determined to be needed. This also further distinguishes provided historical subject compliance data from obtained compliance information, as the provided historical compliance from a previous clinical trial is used to generate the compliance threshold which is compared against compliance information obtained during the current clinical trial. Stark does not disclose such a proactive system. As discussed previously Stark does not provide historical compliance data. Without historical data a compliance threshold cannot be generated by quantitative analysis of the historical compliance data. As such, Stark fails to disclose the step of generating at least one preferred compliance threshold as set forth in claims 4 and 48.

Therefore, in view of the above arguments, Applicants request that the rejection to claims 4 and 48 under 35 USC §102 be withdrawn and claims 4 and 48 be passed to issue.

Claims 5-7

Claims 5-7 depend from claim 4 and as such incorporate each and every element of claim 4. As set forth above, Stark fails to disclose each and every element of claim 4. Thus Stark fails to disclose each and every element of claims 5-7. As such, Stark does not anticipate claims 5-7.

Therefore, in view of the above arguments, Applicants request that the rejection to claims 5-7 under 35 USC §102 be withdrawn and claims 5-7 be passed to issue.

Claims 8 and 49

Amended claim 8 is a method claim and amended claim 49 is a medium claim with instructions for executing the method of claim 8. Stark fails to disclose each and every element of amended claims 8 and 49.

As discussed above in regard to claim 4 and 16, Stark fails to disclose the step of providing historical subject compliance data from a previous clinical trial. For much the same reason as set forth in relation to amended claims 4 and 48 Stark also fails to disclose the steps of generating at least one algorithm reflective of the historical subject compliance data and

translating the at least one algorithm into at least one decision rule for analyzing subject compliance. As previously stated, without proved historical compliance data nothing can be generated from the historical compliance data. As such, Stark fails to disclose the step of generating at least one algorithm and translating the least one algorithm into at lest one decision rule.

Also as discussed above, the present invention is directed to a proactive compliance methodology. That is, decision rule is used to determine if a patient is in compliance during a current clinical trial and whether corrective action needs to be taken. Stark does not disclose such a proactive system. Stark merely analyzes the data to determine compliance to an exercise regimen and makes the next prescribed regimen more difficult as the shows patient more success at completing the previously prescribed exercise regimen. Stark doesn't disclose taking corrective action to maintain subject compliance.

Therefore, in view of the above arguments, Applicants request that the rejection to claims 8 and 49 under 35 USC §102 be withdrawn and claims 8 and 49 be passed to issue.

Claims 9-13

Claims 9-13 depend from amended claim 8 and as such incorporate each and every element of amended claim 8. As set forth above, Stark fails to disclose each and every element of amended claim 8. Thus Stark fails to disclose each and every element of claims 9-13. As such, Stark does not anticipate claims 9-13.

Therefore, in view of the above arguments, Applicants request that the rejection to claims 9-13 under 35 USC §102 be withdrawn and claims 9-13 be passed to issue.

Claims 14, 16, 24, 50-52

Amended claims 14, 16, and 24 are method claims and amended claims 50-52 are medium claims with instructions directed to the methods set forth in amended claims 14, 16, and 24 respectively. Stark fails to disclose each and every element of amended claims 14, 16, 24, and 50-52.

Each of claims 14, 16, 24, and 50-52 recite the steps of providing historical compliance data from a previous clinical trial, generating either a spectrum of compliance or an algorithm from the historical compliance data for use during a clinical trial, and comparing subject compliance information to the spectrum of compliance or a rule translated from the algorithm during the clinical trial. As discussed above in regard to claims 4, 8, 48 and 49, Stark fails to disclose providing historical compliance data from a previous clinical trial and generating and algorithm or the like from the historical compliance data. Also as discussed above, Stark fails to disclose a proactive system or methodology wherein compliance information is compares to a rule or the like during the current clinical trial to determine in action is needed. Thus, for all the reasons above, Stark fails to disclose each and every element of claims 14, 16, 24, and 50-52.

Therefore, in view of the above arguments, Applicants request that the rejection to claims 14, 16, 24, and 50-52 under 35 USC §102 be withdrawn and claims 14, 16, 24, and 50-52 be passed to issue.

Claims 15, 17-23, 25-30

Claims 15, 17-23, 25-30 depend from amended claims 14, 16, and 24 respectively and as such incorporate each and every element of amended claims 14, 16, and 24 respectively. As set forth above, Stark fails to disclose each and every element of amended claims 14, 16, and 24. Thus Stark fails to disclose each and every element of claims 15, 17-23, and 25-30. As such, Stark does not anticipate claims 15, 17-23, 25-30.

Therefore, in view of the above arguments, Applicants request that the rejection to claims 15, 17-23, 25-30 under 35 USC §102 be withdrawn and claims 15, 17-23, 25-30 be passed to issue.

Claim Rejections – 35 USC § 103

Claim 12 is rejected under 35 U.S.C §103(a) as being unpatentable over Stark as applied to claim 8 and further in view of Smith (Smith, G., “Statistical Reasoning.” Third edition. Ch. 15, pgs. 619-667. Allyn and Bacon, a Division of Simon and Schuster, Inc. Needham Heights, MA. 1991, hereinafter “Smith”). Applicants respectfully traverse the rejection.

Claim 12

Claim 12 depends from amended claim 8 and as such incorporates each and every element of claim 8. As discussed above, Stark does not discuss the steps of providing historical subject compliance data from a previous clinical trial, generating at least one preferred compliance algorithm, translating the algorithm into a decision rule for use during a clinical trial, and comparing subject compliance information to the decision rule to during the clinical trial determine if corrective action is needed. The addition of Smith fails to cure this deficiency. Thus, neither Stark nor Smith, alone or in combination, teach or suggest each and every element of claim 8. As such, the combination of Stark and Smith fails to teach or suggest each and every element of claim 12.

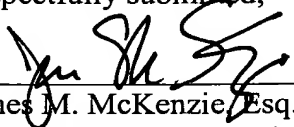
Therefore, in view of the above arguments, Applicants request that the rejection to claim 12 under 35 USC §103 be withdrawn and claim 12 be passed to issue.

CONCLUSION

In view of the above amendment, applicant believes the pending application is in condition for allowance.

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Respectfully submitted,

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